

Implantable MIGS Devices Sub-Conjunctival Space

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Disclosure: I have no financial interest in the material covered in this lecture

Alcon: C,L,S

Aeon Astron: S,C

Endo Optiks: C

Glaukos: S

InnFocus: C

iScience: C

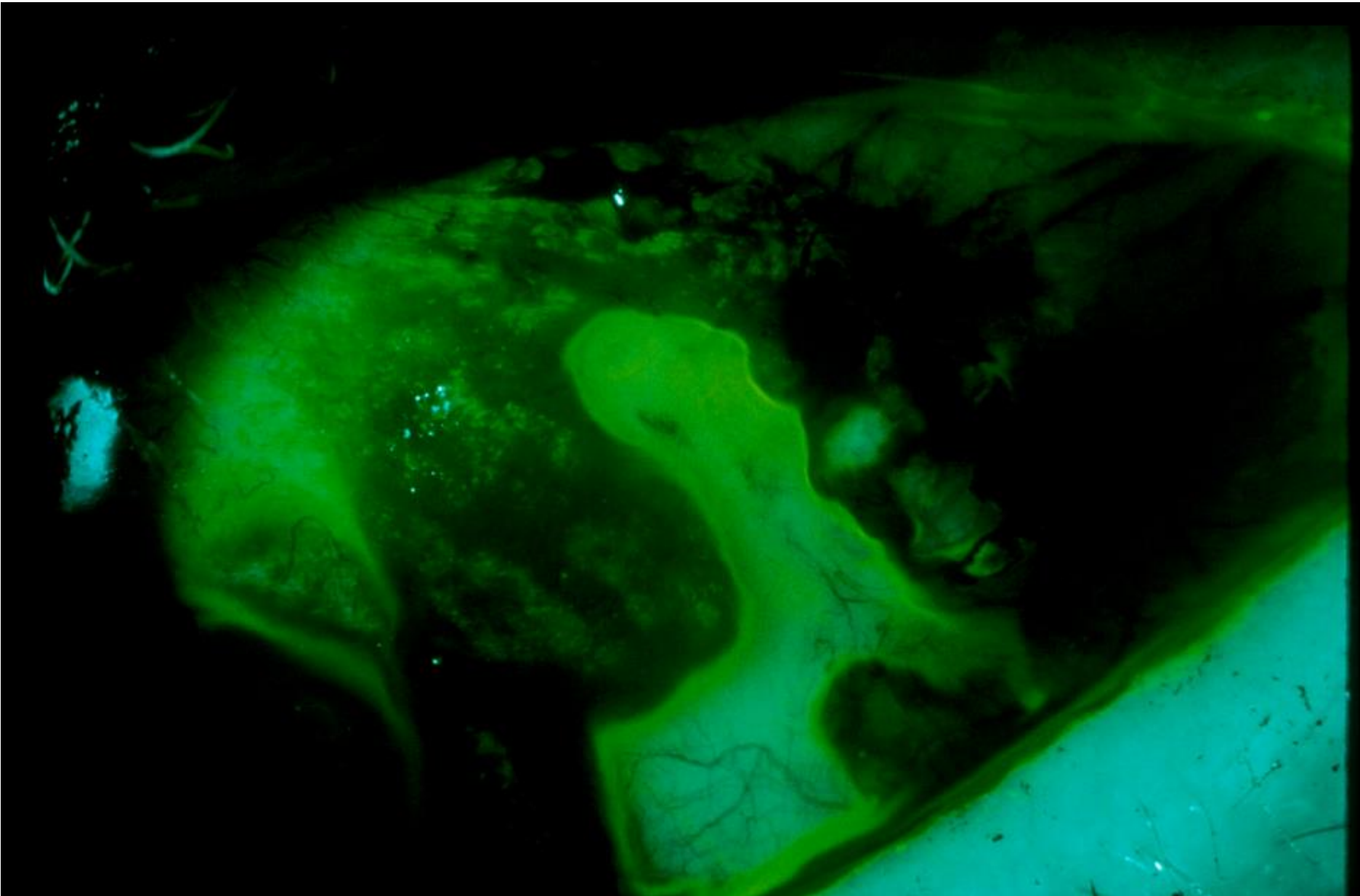
Ivantis: C

New World Medical: C

SightSciences: O

Transcend: S

Trabeculectomy! What's the big deal?



Common Complications from Trabeculectomy

- Endophthalmitis/Blebitis
- Bleb leak
- Hypotony
 - Maculopathy
 - Choroidal Effusions/Hemorrhage
- Bleb Dysaesthesia
- Astigmatism

The Aquasys Xen Gel Stent

- Currently, the only true MIGS device being investigated that is implanted into the subconjunctival space.
- Ab interno implantation
- Soft, compressible implant that is the size of a human hair
- Bypasses the conventional outflow pathway by filtering aqueous into the subconjunctival space.

XEN Materials

- Hydrophilic cylindrical implant of porcine gelatin, cross-linked with glutaraldehyde (to become permanent)
- Hydrates and swells, creating a soft, non-inflammatory drainage channel that is tissue conforming
- 6mm long, with targeted IOP design via Poiseuille's Law (laminar flow)

$$\Phi = \frac{dV}{dt} = v\pi R^2 = \frac{\pi R^4}{8\eta} \left(\frac{-\Delta P}{\Delta x} \right) = \frac{\pi R^4}{8\eta} \frac{|\Delta P|}{L}$$



XEN One-Handed Injector

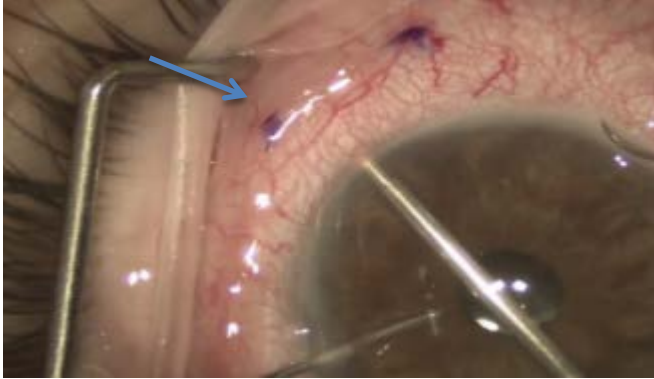
Pre-loaded, Disposable, "IOL-Like" Inserter

- Inserter Sleeve
 - Longitudinal placement guidance (leaves approx. 1 mm of the implant in the anterior chamber)
 - Needle retracts into sleeve after implantation
 - Acts as a safety mechanism for the angle
- Needle
 - 27 gauge, double beveled needle
 - Provides force to pass through the angle to the SC space
 - Angle of the needle is almost parallel to the conjunctiva
 - Needle's angle design significantly reduces risk of puncturing the conjunctiva

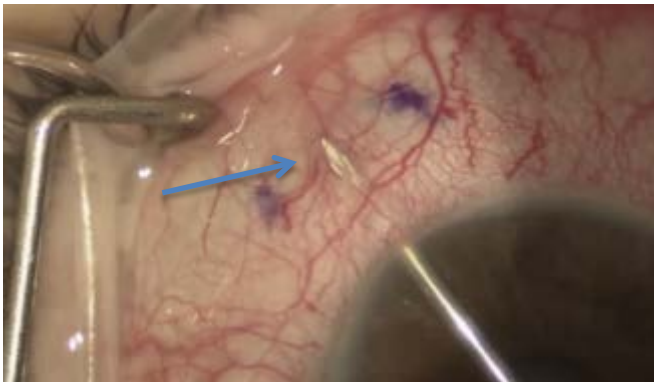


XEN Placement

1. Conjunctiva Sparing: Ab interno placement



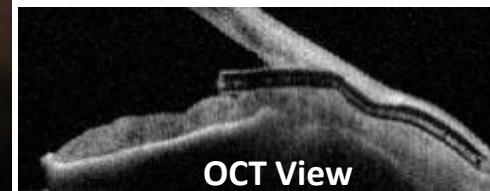
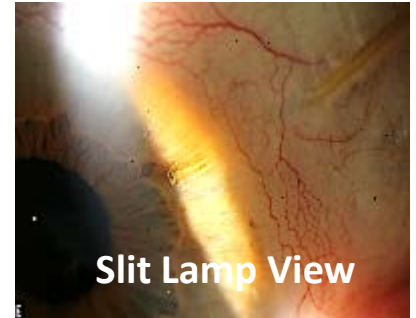
2. Needle bevel exits sclera but stays under conjunctiva



3. Implant positioned with ~2 mm in the subconjunctival space



4. 3 mm intrascleral and 1 mm in the anterior chamber

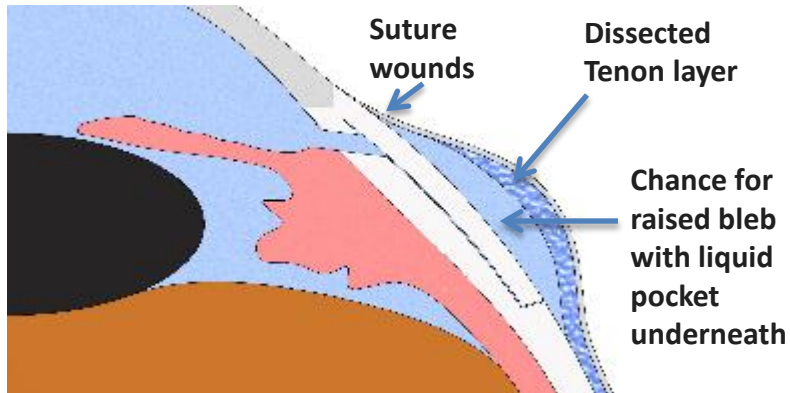


Video of Xen Implant



Ab Externo Bleb vs.

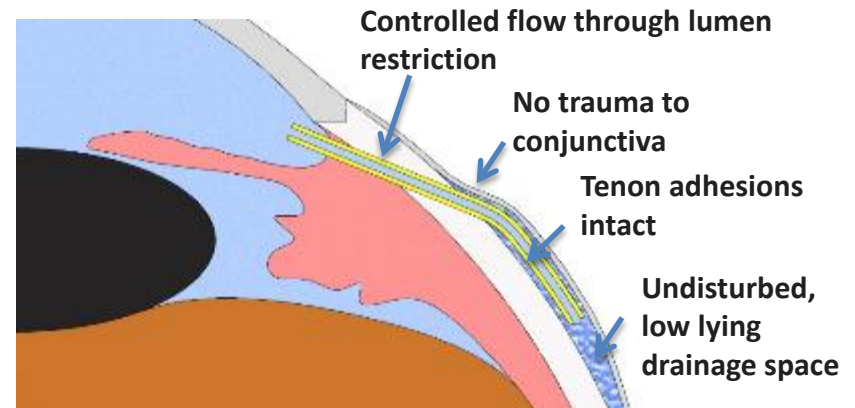
After Trabeculectomy/Express



- Elevated and focal due to ab externo dissection
- Superficial and Thin Walled Bleb
- Higher potential risk for complications

XEN Ab Interno Bleb

After XEN



- Low lying and diffuse due to ab interno
- Deep intra tenon's bleb
- Lower potential risk for complications

Current Global Status

- The **XEN Gel Stent** is an investigational device within the U.S.
 - AqueSys is conducting two studies in refractory glaucoma subjects in the U.S. (stand-alone procedure)
 - One study completed enrollment and follow-up is ongoing
 - Second study is currently enrolling subjects
- The **XEN Gel Stent** has obtained the CE Mark in Europe
 - Phase IV studies are ongoing
 - Limited commercial launch underway

Thank You!

- Implantable MIGS
- Subconjunctival Space
- Steven R. Sarkisian, Jr., MD
- Dean McGee Eye Institute
- University of Oklahoma College of Medicine